REMARKS

Applicants thank the Examiner for the interview and the opportunity to discuss the rejections of December 18, 2006. We first provide comments specifically targeted to issues raised during the February 27, 2007 interview:

With Regard to the 35 U.S.C. 112 Rejections and the Definition of "Insertion Loss"

In accordance with the Examiner's suggestions, we have amended paragraph 37 of the specification to more clearly to specify that the insertion loss, or insertion effect, is the difference between Real Ear Unoccluded Response and Real Ear Occluded Response. The Examiner also suggested that the inventor, Dr. Bauman, provide a declaration indicating that the specification and the claims relate to insertion loss, as distinguished from insertion gain. Such declaration is provided herewith.

We understand that this issue is now resolved. Withdrawal of the rejection is respectfully requested.

With Regard to the 35 U.S.C. 103 Rejections and Pluvinage

a) During the interview, the Examiner contended that: 1) there is motivation to remove the microphone sampling tube of Pluvinage; and 2) that Pluvinage would work just as well without the microphone sampling tube. Immediately subsequent to the interview, Dr. Berlin added comments specifically rebutting these contentions directly into his declaration.

In relevant part, Dr. Berlin identified exactly how the microphone sampling tube is **ESSENTIAL** to Pluvinage. In paragraph 8(a), Dr. Berlin indicates that "***BOTH tubes are required, one to record ambient sound through the resonance peaks of the ear canal and the other to bring sound from the processor (described later as a multiband compressor...) to the speaker or receiver in the ear canal.***"

In paragraph 8(b), Dr. Berlin notes that the purpose of the second tube was ***essential*** to the device's multipurposes...***to use the ear's natural resonances*** to shape and color the incoming speech, to use the ***microphone in the ear to sense and correct for feedback***, (section 8 lines 27-39 and elsewhere)...and to ***receive and compare a plurality***

of signals (Column 7 Lines 6-16). All of this speaks to and refutes the Examiner's contention that the second microphone and/or tube could be removed with no real changes to the device. ***In light of Dr. Berlin's rebuttals, the Examiner's contention is clearly not supportable.*** Reconsideration and withdrawal of the rejections based on Pluvinage are respectfully requested.

Dr. Berlin goes on to indicate in paragraph 8(c) that in their discussions, the Examiner discounted the contents of the processor as being "unknown". However, Dr. Berlin noted that it actually was clearly described in the text as a ***Wide-dynamic range compressor*** (See Columns 6 lines 48 to 67: Column 7 lines 6 –16), which he recognized to be a ReSound ™ hearing aid, ubiquitous in the early 90s as the best device available for ordinary sensori-neural loss.

Dr. Berlin notes: "***The adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube. This sound tubes creates a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response.***"

In paragraph 8(e), Dr. Berlin unequivocally states, "**In summary, the device would not work as intended without the second tube.**"

Keeping all of Dr. Berlin's statements in mind, it is clear that, not only would one of ordinary skill in the art **NOT be motivated** to remove the microphone sound tube, the described hearing aid is **REQUIRES** the microphone sound tube. Thus, there can be no motivation to modify Pluvinage. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As noted by Dr. Berlin, there is no motivation in Pluvinage to remove the sound tube (By direct contrast, the sound tube is ESSENTIAL). Reconsideration and allowance of the claims in light of Dr. Berlin's declaration are respectfully requested.

Dr. Berlin also noted that the hearing aid ***would not work as intended*** without the second tube. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or

motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). As indicated by Dr. Berlin, removal of the microphone sound sampling tube would render the device unsatisfactory for its intended purpose and/or change the principle of operation of the device. **This is a direct indication that there can be no motivation to modify Pluvinage.** Reconsideration and allowance are respectfully requested.

The Examiner also noted a belief that removal of the sound tube would be inherent in light of the Pluvinage reference. However, we have noted Dr. Berlin's comments indicating how the microphone sound tube is ESSENTIAL to the Pluvinage hearing aid. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Because the sound tube is ESSENTIAL to Pluvinage, the lack of that sound tube ***cannot "necessarily flow"*** from the teachings of Pluvinage. Reconsideration and allowance of the claims are respectfully requested.

With Regard to the Evidence of Copying

During the Interview, the Examiner also indicated a belief that in order to validate evidence of copying, the applicant must submit evidence that the competition conducted extensive research into finding their own solution before copying the invention. **This is not true.** As we noted in the interview, this would be impossible, considering that competitors ***do not publish*** their internal research and development plans and results. ***Such a requirement would render the purpose of evidence of copying completely moot for purposes of examination in front of the Patent Office.***

The Examiner may be referencing MPEP 716.06, which cites Dow Chemical

without any comment: Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987). This cite comment is specific to Dow Chemical; it does not define a test for all evidence of copying.

Note the Decision before the Board of Appeals in *Ex parte DONALD G. GILLIS and DANIEL JOHNSON*, Appeal No. 2004-1753, Application No. 09/524,086, page 5, http://www.uspto.gov/go/dcom/bpai/decisions/fd041753.pdf. In that decision, the Board noted that the Examiner improperly failed to consider the evidence of secondary consideration. With regard to the evidence of copying, the board cited a declaration of inventor Gillis that illustrated that major suppliers in the industry copied the applicant's invention. ***The Board validated this evidence, but did not require evidence that those competitors conducted their own research and development prior to copying the applicant's invention.***

The Court in *Buildex Incorporated V. Kason Industries, Inc.*, also recognized that evidence of copying itself (without reference to failure of others) is viable in stating, "It is also significant that no one had designed a hinge like the 2850T for many years but that Kason introduced the 1263 shortly after the 2850T appeared." 665 F.Supp. 1021, 4 U.S.P.Q.2D 1803 (E.D. New York, 1987), citing *Allen Archery, Inc. v. Browning Manufacturing co.*, 819 F.2d 1087, 1092 (Fed.Cir.1987) (significance of copying); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F.2d 617, 620 (Fed.Cir.1987) (same); *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1480 (Fed.Cir.1986) (same); *cf. Panduit Corp. v. Dennison Manufacturing Co.*, 810 F.2d 1561, 1571 (Fed.Cir.1987) (defendant copied inventions).

Similarly, the Court in *Vandenberg v. Dairy Equipment Co.* indicated that "the copying of an invention may constitute evidence that the invention is not an obvious one." 740 F.2d 1560, 1567 (Fed. Circ. 1984), citing Troy Co. v. Products

Research Co., 339 F.2d 364, 367 (9th Cir. 1964), cert. Dismissed, 381 U.S. 930 (1965). The Vandenberg court further stated "this would be particularly true where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed") *Id.*

Thus from the above, it is clear that evidence indicating failures of others to produce a solution is ***not essential*** to validate evidence of copying. Rather, it is merely supplemental to such evidence of copying. Proper consideration of the evidence of copying is respectfully requested.

A Comprehensive Addressing of the Rejections

With regard to the rejections, Applicants provide herewith declarations of independent experts in the field of Audiology. Even a brief review of each of these experts Curriculum Vitae show that these two independent experts are in the top of their profession. Each of these experts comment both on the prior art rejections, and substantiate the viability of the secondary consideration evidence, including the evidence of commercial success, long felt need and copying.

The rejections will be addressed roughly in turn, with the exception of the 35 U.S.C. 112 and 35 U.S.C. 103(a) rejections of claims dealing with the maximum lateral dimensions of the receiver relative to the maximum lateral dimension of the ear canal, which rejections will be addressed at the end of this proposed response.

The 35 U.S.C. 112 Rejections Concerning the Term "Insertion Loss"

Claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 were rejected under 35 U.S.C. 112, paragraph two, as being indefinite with regard to the term "insertion loss." It is immediately noted that during the last interview with the Examiner, this term was differentiated from the term "insertion gain." The Examiner suggested amendment of paragraph [0037] to specify that the insertion loss, or insertion effect, is the difference between Real Ear Unoccluded Response and Real Ear Occluded Response. The Examiner also suggested that the inventor, Dr. Bauman, provide a declaration indicating that the specification and the claims relate to insertion loss, as distinguished from

insertion gain.

We understand that this issue is now resolved. Nevertheless, we will detail how the specification relates to insertion loss rather than insertion gain:

In the December 18 office action, the Examiner attempted to equate the "insertion loss" as described and claimed by the Applicant with the "insertion gain" described by U.S. Patent No. 5,987,146 to Pluvinage (hereinafter "Pluvinage"), and in particular the insertion gain described by Figure 11.

During the last office action, the Examiner conceded that: 1) the Applicant described and claimed "insertion loss"; and 2) that Pluvinage described "insertion gain." The Examiner also recognized that insertion loss is always measured with the hearing instrument turned off, whereas insertion gain is always measured with the hearing aid turned on. The Examiner did contend, however, that insertion loss and insertion gain could be equated at high sound pressure levels (SPLs). We disagree; and more importantly, the independent experts disagree.

Reference is made to the Declaration of Dr. Charles Berlin, paragraph 2, for a description of "insertion loss", "insertion gain", and the incompatibilities of those distinctly different measurement types. Reference is also made to the Declaration of Dr. Glaser, paragraph 10, for a similar description of insertion loss.

In paragraph 2, (b) and (c), Dr. Berlin first notes how Real Ear Unaided Response (REUR) measurements are performed. This measurement forms the baseline for either "insertion loss" or "insertion gain" measurements.

In paragraph 2, (d), Dr. Berlin indicates that insertion loss is measured with the hearing aid turned off, wherein the absolute value of the difference of the sound measured with the hearing aid in place and the REUR is the insertion loss.[1]

In paragraph 2, (j), Dr. Berlin indicates that insertion gain must be measured with the hearing aid turned on. Dr. Berlin also indicates that insertion gain and insertion loss cannot be considered the same thing (Insertion gain can drop to zero if the amplifier is exerting a compression function, but this does not equate to zero insertion loss).

---

[1] As a sidebar, it is also noted that Dr. Berlin indicates that open or vented molds (as in Feeley) present measurable insertion losses, whereas the Vivatone device presents almost no insertion losses (See paragraph 2, (g) and (i)).

Insertion gain is an amplification/compression function that bypasses any obstruction in the ear canal caused by the hearing aid. If one were to place a speaker inside a room and feed a microphone source from outside the room, measurement of the sound from that speaker has no bearing on how thick or acoustically transparent the door is. That is, a hearing aid may have zero or near zero insertion gain by virtue of a compression function, but still have substantial insertion loss by virtue of its size in the ear canal. Pluvinage does not teach three decibels or below of insertion loss.

Dr. Glaser also indicates that insertion loss and insertion gain, as used by Pluvinage, are not comparable (see paragraph 11 of Dr. Glaser's declaration).

In sum, the Applicant describes and claims insertion loss and not insertion gain. Further, because of the nature of the two terms, insertion loss and insertion gain are not comparable (this has further relevance with regard to the Pluvinage rejections, discussed below).

The 35 U.S.C. 103(a) rejections With Regard to Pluvinage

Claims 1-7, 40, 42-53, and 59-63 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage.

Of primary point, we note that Pluvinage does not teach the following limitation: "the receiver generating ***about three decibels or below of insertion loss*** over a portion of the human ear audible frequencies." The Examiner uses Pluvinage as its sole reference in this regard. More specifically, the Examiner equates the term "insertion gain" as used by Pluvinage in Figure 11 and Col. 8, lines 15-25 is the same thing as the insertion loss as described and claimed by the Applicant. The Examiner also indicates that the claims are indefinite in this regard because of "things like non-linear varying unoccluded responses of ears and variability of stimulus."

As we have noted above, the presently claimed subject matter relates to insertion loss, not insertion gain. Reference is made to Dr. Berlin's declaration at paragraph 2(j), which teaches the differences between insertion loss and insertion gain. Insertion loss does not vary according to SPL (this is because it is measured with the hearing instrument turned off). It is absolutely a measurement related solely to size of the hearing aid in the

ear (no amplification function, no compression function). Accordingly, the claims are definite.

The Examiner also indicates that the "insertion loss" term is a mechanism of defining structure according to function. This is not so. The Vivatone insertion loss is a characteristic of the open ear Vivatone system, which comprises a small speaker suspended in the ear and connected to the BTE via a thin wire.

With regard to the "about three decibels or below of insertion loss limitation", reference is made to Dr. Berlin's Declaration at paragraph 7 and Dr. Glaser's Declaration at paragraph 11. Therein, the independent experts clearly indicate that Pluvinage does not teach about three dB or below of insertion loss. Pluvinage's teachings about insertion gain ***can have no bearing*** on insertion loss. At paragraph 6, Dr. Berlin indicates that the described Pluvinage system, which requires multiple tubes/components side by side in the ear canal, significantly occludes the ear canal relative to the Vivatone configuration (indeed, because of this significant occlusion, it would make sense that this system would generate significant insertion loss).

Dr. Glaser similarly indicates, at paragraph 11, that Pluvinage does not teach three decibels or below of insertion loss or that, in a switched off mode, the side-by-side profile would generate three decibels or below of insertion loss.[2]

Because the three decibel or below of insertion loss limitation is not taught or suggested by Pluvinage, a prima facie case of obviousness has not been made out. Reconsideration and allowance of the claims are respectfully requested.

Further, as noted by Dr. Berlin's declaration, paragraph 6, removal of the sound sampling tube was not an obvious change at the time of the Pluvinage application. Specifically, Pluvinage **REQUIRED** the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements*. Because the proposed modification is improper, we again respectfully request reconsideration and allowance of the claims.

---

[2] Dr. Glaser also indicates (even though Pluvinage's measured insertion gain has no bearing on its insertion loss) that even at 80 dB SPL, for certain frequency ranges, Pluvinage's insertion gain is shown to be greater than 3dB in Figure 11.

Dr. Glaser also noted, at paragraph 13 of his declaration, that an audiologist possessing ordinary skill in the art would not have been motivated to modify the Pluvinage device to achieve the Vivatone hearing aid system. Dr. Glaser also notes that Pluvinage ***requires*** *both delivery of and sampling of sound within the ear canal.*

Because the requisite motivation to modify the Pluvinage device is lacking, as independently confirmed by two experts in the field, reconsideration and allowance of the claims are respectfully requested.

The foregoing also makes sense with regard to Pluvinage's best mode requirement. Pluvinage believes that its multi-component configuration is ideal. Indeed, as noted by Dr. Berlin, Pluvinage ***requires*** the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements.* Pluvinage clearly disclosed its best mode, ***which requires the microphone tube or microphone in the ear canal*** (indeed, Pluvinage was obligated to).

Pluvinage did not disclose the Vivatone system (if Pluvinage believed such a system was better, it would have and should have disclosed it). Because Pluvinage **REQUIRES** the microphone tube or microphone in the ear canal, and/or because there is no motivation within Pluvinage to remove the sound tube to essentially find the Vivatone system (the prohibition against hindsight reconstruction and using the Applicant's own specification as a roadmap is reiterated), the rejection is improper.

In sum, the Pluvinage system 1) does not teach or suggest the "three decibels or below of insertion loss" limitation; 2) would not work as intended should the microphone tube be removed, as has been suggested by the Examiner; and 3) does not provide motivation to make such a change. Further, Dr. Berlin and Dr. Glaser each noted Pluvinage's ***requirement*** for the sound tube ***and the lack of motivation*** within Pluvinage or within the art to remove that sound tube.

As to the Examiner's assertion that one skilled in the art would be motivated to remove the sound tube ***to avoid infringing the Pluvinage claims***, both Dr. Berlin and Dr.

Glaser noted that they would ABSOLUTELY not have known to do this, since they are not patent lawyers. They would not have even been thinking along those lines.

Indeed, the Examiner's assertions would mean that "one of ordinary skill in the art" would necessarily have to be a licensed patent attorney, having the training and ability to perform claim construction of claim terminology based on the specification and the prosecution history in order to understand whether a product that they might dispense would potentially infringe (assuming they even cared). To require "one of ordinary skill in the art" to be a patent lawyer goes completely against the plain language and purpose of looking to the understanding of "one of ***ordinary*** skill in the ***art***" when assessing motivation to combine references or otherwise modify a teaching. In this case, the "***art***" is Audiology, not patent law. Further "one of ***ordinary*** skill" in Audiology is not a patent lawyer turned Audiologist, or an Audiologist turned patent lawyer; it is an Audiologist. Reconsideration and allowance of the claims are respectfully requested.

The 35 U.S.C. 103(a) Rejection Combining Feeley, Fretz and Pluvinage

The Examiner rejected claim 1 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2004/0010181 to Feeley (hereinafter "Feeley") in view of U.S. Patent Publication No. 2003/0002700 to Fretz (hereinafter "Fretz") and further in view of Pluvinage.

Essentially, the Examiner indicates that Feeley does not teach the Applicant's invention because: 1) Feeley requires a mold; and 2) Feeley does not teach the "three decibel or below of insertion loss" limitation of claim 1. The Examiner then indicates that Fretz teaches that blocking of the ear canal can be undesirable, and that venting of molds may not be sufficient.

The Examiner then makes a mental leap by saying that, based on the teachings of Fretz, it would be obvious to do away with the Feeley mold and suspend a speaker in the ear canal. ***However, Fretz did not teach this.*** Fretz's alternative to molds was to route a ***sound tube*** from a BTE into the ear canal. Sound tube BTEs are known.

Feeley's design is from a different class (BTE plus mold). Feeley taught that the mold should preferably be inserted deep within the ear canal such that it touches the bony

portion of the ear canal (thus avoiding the occlusion effect). While Feeley does teach that venting may be used, it does not indicate that removal of the mold would be beneficial or desirable (indeed, Feeley requires the mold).

*Feeley does **not** indicate or suggest a solution better than a deeply inserted mold in the ear canal (vented or not). Fretz does **not** indicate or suggest a solution better than routing a sound tube from a BTE into the ear canal.* There is no motivation to combine these references.

The Examiner also indicates that the Feeley receiver may be replaced with "any Knowles receiver", as per teachings in Pluvinage. Even if this were the case, it would still be a Knowles receiver secured within a mold (since Feeley requires a mold).

All of the above is reinforced by the declarations of both independent experts, Dr. Berlin and Dr. Glaser. Each indicates that the proposed modification is unsupported by motivation from the references and the art.

Specifically, Dr. Glaser notes, at paragraph 14, that the Vivatone system is **not** an obvious modification of the Feeley System nor the system described by Fretz.

Dr. Berlin similarly indicates, at paragraph 8, that Feeley and Fretz are disparate solutions, and that one of ordinary skill in Audiology would **not** be motivated to change the CIC device of Feeley. As stated by Dr. Berlin, "Feeley does not describe suspending a speaker in the open ear in any way, the ear canal is not open, and the term 'open mold' merely describes a mold vent." Feeley is not, "and does not suggest the essential Vivatone configuration."

In sum, both independent experts positively declared that one of ordinary skill in the art would not be motivated to modify Feeley with the teachings of Fretz (The Figure 11 teachings of Pluvinage having been addressed above) to result in the Vivatone configuration. The art does not in the least teach or suggest suspending the receiver of Feeley in any way for an open ear receiver fit. Reconsideration and allowance of the claims are respectfully requested.

The Examiner's Attempted Rebuttal of the Secondary Consideration Evidence

In the December 18, 2006 office action, the Examiner laid out a lengthy rebuttal

of all of the secondary consideration categories presented by the Applicant, including the evidence of commercial success, the evidence of copying by others, and the evidence of long felt need.

Subsequent to the last office interview, we consulted the independent experts, Dr. Berlin and Dr. Glaser, in order to get an understanding of: 1) whether experts in Audiology would consider the Vivatone product to be successful; 2) whether experts in Audiology would consider Oticon, Hansaton, Interton, Siemens and Phonak to have copied Vivatone (rather than copying Feeley or Pluvinage designs); and 3) whether Vivatone really satisfied a long felt need in the industry (i.e., how did experts view the introduction of the Vivatone product (as just another product, or really a new category solving all sorts of needs in the art)). As will be discussed in detail below, each independent expert wholly validated the Vivatone product's commercial success; both refuted the Examiner's contention that Feeley or Pluvinage was copied (rather than Vivatone) and positively indicated that Vivatone was copied; and indicated that the Vivatone product was, indeed, a new category, revolutionary, etc., in the hearing aid industry.

The Evidence of Commercial Success

Both Dr. Berlin and Dr. Glaser positively declared that they considered the Vivatone hearing system commercially successful, despite minimal advertising, no name recognition, and market derived bars to entry (i.e., penetration of the market despite things like distributor loyalty to large manufacturers, large advertising campaigns by competitors, etc.).

The Vivatone Hearing Aid Was Revolutionary; A Head Turner

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivatone product as "a clever design that unequivocally turned heads in the Audiology community." Indeed, Dr. Glaser indicates that Vivatone "has done quite well in the marketplace because of their unique configuration and product presentation (the small BTE

component with the microphone port, the thin speaker wire, and the small speaker suspended in the ear canal)." Thus, Dr. Glaser ties Vivatone's commercial success directly to key aspects of Vivatone's open design and positively indicates that the Audiology community saw the Vivatone hearing aid as "clever" and "a head turner."

We note that the Examiner expressed a belief that the Vivatone System was not the type of product that would be a head turner (the "I've got to have it" type of product similar to the Ipod). Dr. Glaser's declaration refutes the Examiner's claim. Dr. Berlin's declaration also directly refutes this in paragaph 13, indicating that the Audiology community could ***immediately see the unique value of the Vivatone system*** (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages).

Dr. Berlin emphatically described the Vivatone product as "***revolutionary***", indicating that when he first saw the product in 2004, he felt that it would "***change the industry***." (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivatone product would "***change the way hearing aids are made and distributed***." (paragraph 11).

Vivatone's Commercial Success was Phenomenal; Sales Soared

Dr. Berlin also indicated that Vivatone's ***commercial success was "impressive,*** particularly because Vivatone spent very little on advertising and had no broad name recognition in the industry." He also indicated that "***most small companies fail for those same reasons***." (See paragraph 11 of Dr. Berlin's declaration).

Dr. Glaser similarly declared that Vivatone's ***product sales "soared before similar competing products were introduced***." Dr. Glaser noted that sales soared "***despite*** the fact that most Audiologists have *fairly strong ties to certain manufacturer's product lines* and ***despite*** the fact that Vivatone did *little direct advertising*" (citing *word of mouth industry buzz* /re Vivatone's product).

In sum, both experts cite substantial commercial success despite bars to market penetration for small companies (including little advertising, audiologist ties to existing manufacturer's product lines and lack of name recognition).

Advertising Directly Affects Sales

Both experts also discount the Examiner's contentions that the hearing aid industry is not affected by advertising (because advertising in the marketplace does not directly affect sales). Dr. Berlin ***directly refutes*** this statement in paragraph 12, citing Miracle Ear ads on CNN, and Beltone and Siemen's television advertising schemes. Referring to the Examiner's contentions, Dr. Berlin DIRECTLY states: "**Vivatone's commercial success was** driven by word-of-mouth referral and was **phenomenal** (despite minimal advertising). **It should not be discounted.**"

Dr. Glaser points to the need and activity of manufacturers in "*marketing their products to audiologists and hearing aid dispensers.*" (see paragraph 16). Dr. Glaser positively states, "**The hearing aid industry is heavily affected by advertising.**" He continues, "**Marketing to professional audiologist as well as the consumers is an extremely expensive proposition within the hearing aid industry. As such, Vivatone's commercial success should be seen as even more remarkable because of the fact that Vivatone's advertising expenditures were so minimal.**"

The Examiner also quoted Alan Dozier from GN Resound, who stated "Not a lot of consumer advertising is being done to build confidence in hearing aid instruments and build brand awareness." Dr. Glaser positively agrees with the statement as it relates to conventional hearing aids, but "***completely disagrees***" as it relates to Vivatone, which is a "***new category of hearing aids.***" (see paragraph 16 of Dr. Glaser's Declaration). Dr. Glaser further states that the Vivatone product "***has spurred a change in the hearing aid industry as it relates to marketing efforts. Indeed a great deal of advertising is now being done for this category (a 'this is not your father's hearing aid' type of response to the Vivatone configuration).***" Dr. Glaser cites the marketing materials of Oticon, Siemens, Hansaton, Interton and Phonak as exemplary.

Dr. Berlin similarly indicates that Alan Dozier's statement ***does not relate*** to "this new category of hearing aids." Dr. Berlin also cites the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as ***directly reflective of industry change resultant from Vivatone's "revolutionary design."*** (see paragraph 14 of Dr. Berlin's Declaration).

The Revolutionary Nature of Vivatone Does Not Allow For Comparison With Conventional Designs (Re Market Data)

Related to Dr. Berlin's and Dr. Glaser's comments immediately above, the Experts do not consider Vivatone's market share to be comparable to other conventional categories of hearing aids, such as BTE-tube designs or BTE designs in general.

Dr. Glaser notes, near the end of paragraph 16, that "***comparison of the open canal Vivatone system*** (and the similar Oticon, Hansaton, Siemens, etc. systems) ***with conventional BTE tube systems*** is...not really effective (it is the ***'apples to oranges'*** comparison)." Dr. Glaser positively indicated that the Vivatone system was a "***new category of hearing aids***." (see paragraph 16 of Dr. Glaser's Declaration).

Dr. Berlin similarly stated, "Vivatone is ***simply not comparable*** to other devices..." (paragraph 11). Dr. Berlin also stated, **"the revolutionary nature of the Vivatone system does not allow for comparison with conventional designs (even with "open fit" tube designs, which are a subcategory of the BTE category)."**

Accordingly, Vivatone held the entire market share of this new category, until Oticon, Hansaton, Siemens and others became competitors in this category by copying the Vivatone configuration. **The market data of other categories, even "open fit" tube designs, do not relate.**

In summary, the independent declarations of Drs. Berlin and Glaser can leave no doubt that the Audiology industry considers Vivatone to have enjoyed **phenomenal** and **un-refutable commercial success** by introducing Vivatone, **which the industry considered revolutionary/ the first in a new category of hearing aids/ a product that changed how the hearing aid industry manufactured, distributed and marketed hearing aids.**

The Evidence of Copying by Others

Drs. Berlin and Glaser Indicate Copying by Oticon, Siemens, etc. Rather than Feeley or Pluvinage

Dr. Berlin declared, at paragraph 5, that he considers Phonak, Siemens, Interton, Oticon and Hansaton to have copied Vivatone's essential configuration. Dr. Berlin does note that, "while various versions of these devices may have different or additional features, ***they have all taken Vivatone's essential design*** (***which design I considered and still consider to be revolutionary***), including the small BTE with the microphone port, the thin speaker connecting wire, and the small speaker suspended in the ear canal."

Dr. Glaser also declared, at paragraph 5, that "***since the introduction of the Vivatone hearing aid, other manufacturers have seen fit to produce hearing aids in this category***." Dr. Glaser indicated (paragraph 9) that these competitors have taken the "principal element" of the Vivatone hearing aid design (despite having produced products with additional electronics, software compression, etc.). With regard to these copies of Vivatone, Dr. Glaser concludes, "...**the basis of their offerings in this new class of hearing aids obviously stems from the Vivatone product.**" In paragraph 16, Dr. Glaser states, "...**it is clear to me that the other major manufacturers of hearing instruments have seen fit to copy the product**."

Drs. Berlin and Glaser made the above statements after being made aware of the Feeley and Pluvinage teachings. Despite those teachings, as evidenced by the above, they each independently and firmly believe that the essential Vivatone hearing aid system was copied rather than any of the teachings in the prior art. Dr. Berlin further indicates (paragraph 15) "...devices supposedly patented before Vivatone ***do not directly address*** the ***problems of Occlusion and Insertion loss*** separately ***in the creative manner exemplified by Vivatone***." Dr. Glaser indicates at the end of paragraph 16, "**the Pluvinage instrument also does not compare. The Vivatone system is an advancement in that it rejects the BTE-tube designs as well as the hybridized tube design of Pluvinage.**"

Accordingly, the independent experts ***separately reject*** the Examiner's contention ***that the competitors copied the prior art*** Feeley or Pluvinage teachings, while at the same time ***separately confirm*** that these ***competitors copied the essential aspects of the Vivatone design***.

The Laudatory Statements of Competitors

The Examiner contended that the laudatory statements can be directed not only to the applicant's invention but to the Pluvinage and Feeley hearing aids. However, ***both Drs. Berlin and Glaser indicate the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as directly reflective of industry change resultant from the introduction of the Vivatone product.*** (see Dr. Berlin's Declaration at paragraph 14 and Dr. Glaser's Declaration at paragraph 16). Further, each of the independent experts indicate that these competitors, while they may have varied features, such as additional electronics, software compression etc., ***obviously copied the essential or principal aspects of the Vivatone system (not the prior art).*** (See Dr. Berlin's Declaration at paragraph 5 and Dr. Glaser's Declaration at paragraph 9). **Accordingly, the laudatory comments relate directly to the essential aspects of the Vivatone device, and not the Feeley or Pluvinage devices.**

The Evidence of Long Felt Need

The Vivatone Hearing Aid Was Revolutionary

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivatone product as "a clever design that unequivocally turned heads in the Audiology community."

Dr. Berlin's, in paragraph 13, indicated that the Audiology community could ***immediately see the unique value of the Vivatone system*** (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages). Dr. Berlin emphatically described the Vivatone product as "***revolutionary***", indicating that when he first saw the product in 2004, he felt that it would "***change the industry.***" (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivatone product would "***change the way hearing aids are made and distributed.***"

The revolutionary nature of the product is reflective of the fact that the Vivatone system satisfied a long felt need. As noted by Dr. Berlin, the traditional, long felt problems of Occlusion and Insertion loss, have been obviated by Vivatone's non-obtunding design (paragraph 15).

Independently, Drs. Berlin and Glaser declared that the Audiology industry considers Vivatone's **commercial success to be phenomenal and un-refutable**. They indicated that **Vivatone pioneered a new, revolutionary category of hearing aids** that was **summarily copied by competitors because of Vivatone's unique essential configuration**. Drs. Berlin and Glaser confirmed that both the **copying and laudatory statements originate from Vivatone's unique essential configuration** and not the prior art. Drs. Berlin and Glaser also indicated that the genesis of this copying stems from the **Vivatone hearing aid's unique solution to the long felt problems** of the industry.

Reconsideration and allowance of the claims with specific regard to the secondary consideration evidence are respectfully requested.

The 35 U.S.C. 112 Rejections Relating to Receiver Size

The Examiner rejected claims 10-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner indicates a belief that small receivers could not have been made at the priority date of the present application. As evidence of this, the Examiner cites the Knowles FK series receiver, which has a rectangular cross section with a maximum dimension of 2.73mm (the Examiner indicates a belief that the receiver must be 2.0mm to be enabled). The Examiner relies upon the FK receiver's 1999 manufacture date and believes that because he has not heard of a smaller receiver since then, that such receiver cannot be produced. This ignores the fact that such a receiver could be made, e.g., with a round cross section (the commercial Vivatone has a roughly round cross section).

The Examiner also indicates that claims 8-12, 36-38, 56, 57, 61, 63, 65 and 67 are all indefinite in that they recite that a maximum lateral dimension of the receiver is less than a certain percent of the maximum lateral dimension of a user's ear canal. However, simply because the maximum lateral dimensions of users ear canals vary does not render the claim indefinite. On a per user basis, such measurement may be readily made. Further, as the Examiner attempts to do, such dimensions (more practically) may be based on averages of users (there is a fairly defined range of ear canal dimensions).

The 35 U.S.C. 103(a) Rejections Based on the Receiver Size

Claims 8, 26-29, 35-37 and 54-57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog. Specifically, the Examiner notes the EH series receiver with a dimension of 3.55mm, which the Examiner indicates is less than half of the average opening of the ear canal at 10mm. However, this rejection ignores that the Pluvinage system includes not just a receiver, but also a microphone or microphone tube alongside the receiver (which would also likely include a casing around the bare receiver). Ignoring the probable casing, just the receiver and adjacent microphone or microphone tube would provide for a maximum lateral dimension that would exceed 50% of a user's ear canal lateral dimension. (See the Declaration of Dr. Berlin at paragraph 7 and the Declaration of Dr. Glaser at paragraph 12). Reconsideration and allowance of the claims are respectfully requested.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,

CANTOR COLBURN LLP

By: 

H.M. Bedingfield
Registration No. 44,530
CANTOR COLBURN LLP
55 Griffin Road South
Bloomfield, CT 06002
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No. 23413

Dated: March 15, 2007